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Observations and Conversations: A Mixed Methods Approach to Describing Home-Preparation of Infant Formula among a Sample of Low-Income Mothers

Rebecca Lauren Ellison
University of Tennessee - Knoxville, rgrave13@utk.edu

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I am submitting herewith a thesis written by Rebecca Lauren Ellison entitled "Observations and Conversations: A Mixed Methods Approach to Describing Home-Preparation of Infant Formula among a Sample of Low-Income Mothers." I have examined the final electronic copy of this thesis for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Master of Science, with a major in Nutrition.

Katie Kavanagh, Major Professor

We have read this thesis and recommend its acceptance:

Marsha L. Spence, Melissa Hansen-Petrik

Accepted for the Council:
Dixie L. Thompson

Vice Provost and Dean of the Graduate School

(Original signatures are on file with official student records.)

Observations and Conversations: A Mixed Methods Approach to Describing Home-Preparation of Infant Formula among a Sample of Low-Income Mothers

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ABSTRACT

Background: The obesity epidemic in the United States (US) is a well-established public health crisis associated with immense national healthcare expenditures. The first two years of life represent a potentially critical intervention period for attenuation of inappropriate rapid weight gain and risk of subsequent overweight and obesity in childhood. Low-income mothers in the US are at risk for formula-feeding and early introduction of solid foods, which are behaviors that could lead to excessive rapid weight gain during this critical time period. However, little is known about actual, rather than self-reported, maternal infant-feeding behaviors related to proper infant formula preparation.

Objective: To explore maternal infant formula preparation practices and related knowledge, attitudes, and beliefs, among low-income, formula-feeding mothers of very young infants.

Methods: This study utilized a cross-sectional, mixed methods design. Participants were mothers of normal birth weight, healthy, term infants less than three months of age, who were predominantly formula-feeding with powdered or from-concentrate infant formula, and who were WIC income-eligible. Study activities included home observations of infant formula preparation and in-depth interviews. Descriptive statistics were used to describe the sample demographic characteristics and home-observation variables. Thematic analysis was used to identify themes present in the in-depth interviews. The mixed methods approach was used to triangulate results of both study activities.

Results/Conclusions: Behaviors including over-concentration, over-dilution, modifications/additions to prepared infant formula, and early introduction of solid foods (i.e., cereal added to bottles of infant formula) were observed during the home observations and/or were described during the in-depth interviews. Additionally, there appeared to be inconsistencies

between behaviors observed during formula preparation and those reported in subsequent in-depth interviews. Targeting knowledge and skills gaps along with motivators of maternal behaviors in this population could diminish the prevalence of infant-feeding practices that may predispose infants to inappropriate rapid weight gain.

Keywords: infant formula, maternal behaviors, infant-feeding, motivators, knowledge, skills

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CHAPTER I: LITERATURE REVIEW

The obesity epidemic in the United States (US) is a well-established public health crisis associated with immense national healthcare expenditures.[1-4] Obesity rates among American adults and children have been increasing over the past three decades with a slight leveling off in recent years.[5] However, despite this recent deceleration, approximately 35% of US adults and 17% of US children and adolescents are classified as obese.[5] Therefore, identifying effective interventions to support continued deceleration of these rates is an active area of research.[6-9]

Infancy, or the first two years of life, has been identified as a potentially critical intervention period for attenuation of inappropriate rapid weight gain, as excessive rapid gain has been linked to subsequent overweight and obesity in childhood.[10-15] Since overweight and obese children are more likely to be overweight or obese as adults, preventing inappropriate rapid weight gain during infancy could help decrease national overweight and obesity rates and the associated co-morbidities such as type 2 diabetes and cardiovascular disease.[16-19]

Protective effects of breastfeeding:

For this time period, breastfeeding is recognized as the healthiest mode of infant-feeding.[20] The World Health Organization (WHO) recommends exclusively breastfeeding infants for the first six months of life and continuing breastfeeding up to two years of age.[21] Similarly, the American Academy of Pediatrics (AAP) recommends exclusively breastfeeding infants for the first six months of life and continuing breastfeeding at least one year or as long as mutually desired by the mother and infant.[22] Breastfeeding exclusively means that the infant receives breastmilk only and that no other liquids or solids, including water, are consumed.[21] Following these WHO and AAP recommendations may be protective against excessive rapid weight gain early in life.[10-15]

Dewey and colleagues conducted a landmark study comparing weight-for-length and percent fat mass between exclusively breastfed infants and exclusively formula-fed infants.[23] There were forty-six breastfed infants and forty-one formula-fed infants included in the study, and the researchers controlled for potentially confounding variables such as parental socioeconomic status, ethnicity, maternal education and anthropometric measurements, and infant sex and birth weight.[23] Results indicated that breastfed infants had a significantly lower weight-for-length compared to formula-fed infants between seven and twenty-four months of age, and the greatest difference occurred between eleven and sixteen months of age.[23] Also, the formula-fed infants reached a greater peak in percent body fat compared to breastfed infants during the first year of life.[23] Dewey and colleagues concluded that the probable main contributing factor for these results was the difference in total energy intake between groups.[23] Formula-fed infants on average consumed significantly more kilocalories per day during the first year of life compared to the breastfed infants, with intake ranging from 79 kilocalories to 156 kilocalories more per day for formula-fed infants.[23]

Li and colleagues[24] further explored infant self-regulation to determine if breastfed infants consumed fewer kilocalories per day due to the ability to better self-regulate energy intake, as they are thought to be more in control of when a feed is terminated compared to bottle-fed infants.[25] Therefore, it was hypothesized that infants who were fed expressed breastmilk from a bottle would grow comparably to formula-fed infants, despite differences in milk type.[24] Li and colleagues, using a national cross-sectional dataset, analyzed infant weight status in the first year of life as an outcome of milk type consumed (human vs. nonhuman milk) and feeding mode (breast vs. bottle).[24] They found that bottle-feeding was associated with greater infant

weight status at one year of age, regardless of the type of milk offered.[24] However, the cross-sectional nature of the study does not allow for determination of cause and effect.[24]

In a separate study, Li and colleagues found that infants who were breastfed less intensively (reflecting both exclusivity and duration) during early infancy were at an increased risk for having an excess weight status in late infancy, suggesting that these infants consumed a greater amount of total kilocalories from infant formula and/or expressed breastmilk from a bottle compared to infants who were breastfed more intensively during early infancy.[26] Furthermore, infant weight status during late infancy was positively associated with infant-initiated bottle emptying (the infant consumes all of the bottle contents, despite the composition of the bottle contents and despite lack of maternal encouragement to do so) during early infancy.[26] In this study, 58.3% of the 1,896 mothers who participated reported that their infants emptied their bottles 'always' or 'most of the time', and only 15.6% of the participants reported encouraging their infants to do so.[26] This is important to note, because these results suggest that the total ounces of formula offered to infants may be associated with the total ounces consumed by infants.[26] Therefore, excessive ounces offered to infants could be one mechanism affecting infants' overall caloric intake during early infancy and their associated excess weight status during late infancy.[26]

The prevalence of formula-feeding:

Despite initiatives to increase breastfeeding initiation, duration, and exclusivity rates, many infants in the US are not fed according to these recommendations.[27] According to the Centers for Disease Control and Prevention 2014 Breastfeeding Report Card, about 20.8% of US infants are never breastfed.[27] Additionally, only 40.7% of US infants are exclusively breastfed at three months of age, and a mere 18.8% of US infants are exclusively breastfed at six months of

age.[27] Experts recognize the need to increase national breastfeeding rates, which is reflected by the following Healthy People 2020 Objectives: By 2020, 81.9% of US infants will be ever breastfed (breastfeeding initiated), 46.2% of US infants will be breastfed exclusively at three months of age, and 25.5% of US infants will be breastfed exclusively at six months of age.[28] However, there are barriers to achieving these national goals.[29] For example, some mothers are not able to breastfeed, choose not to breastfeed, or engage in early weaning practices for a variety of reasons.[29,30] Reported reasons for early weaning include the need to return to the workforce, perceived insufficient milk supply, and perceived maternal inconvenience associated with breastfeeding.[29,30] US infants who are not breastfed exclusively during the first six months of life are predominantly offered infant formula as the primary or supplemental source of essential nutrients.[31] Thus, there is a need to explore infant-feeding behaviors among families who are unable to or choose not to breastfeed their infants according to recommendations, so that interventions can focus on decreasing potential excessive rapid weight gain among the large population of formula-fed infants in the US.

Formula-feeding concerns and improper infant-formula preparation behaviors:

Behaviors such as adding infant cereal to prepared bottles of infant formula and early introduction of solid foods contradict infant-feeding recommendations for formula-fed infants less than four months of age and could lead to excessive rapid weight gain during the first year of life.[32-34] Both the addition of infant cereal to prepared bottles of infant formula and the early introduction of solid foods are thought to induce and extend infant sleep, and are behaviors potentially motivated by maternal convenience.[35-37] Mothers also report adding infant cereal to bottles of infant formula in an effort to manage infant reflux.[37,38] Though there is limited evidence indicating a moderate decrease in infant reflux when infant cereal is added to the

formula bottles,[38] this is only indicated in specific, diagnosed situations[39] and is otherwise recommended against for healthy infants.[32,33] In fact, adding infant cereal to bottles of infant formula is thought to increase the risk for dental caries, allergies, and bacterial infections.[33,40-45]

In addition, other practices, such as over-concentration, over-dilution, or too many ounces offered and consumed, may also lead to excess caloric intake, and subsequent excessive rapid weight gain during the first year of life.[46,47] For example, regardless of intent, over-concentration (offering more than twenty kilocalories per ounce of formula) could be one mechanism resulting in undesirable growth trajectories for infants.[48] Low birth weight infants are often offered formula that is greater than twenty-four kilocalories per ounce in order to stimulate rapid weight gain (i.e., "catch up growth").[48] Therefore, theoretically, even a small manipulation in formula concentration, resulting in over-concentration, may eventually lead to excessive weight gain amongst healthy infants.[46] Conversely, over-dilution of formula (less than twenty kilocalories per ounce), regardless of intent, may increase infant hunger, lead to an increase in expressed hunger cues, and ultimately result in more frequent feeds and subsequent excessive rapid weight gain.[25,26] However, the hypothesized association between over-dilution, increased hunger cues, and increased frequency of feeds remains unexplored, so this assumption is not currently supported by research. Thirdly, overfeeding may occur simply by offering too many ounces per feed resulting in increased total consumption.[24,26] Although little research has been conducted regarding incorrect preparation of infant formula and later overweight/obesity,[46] the association is theoretically plausible due to the potential for excess caloric intake per ounce (over-concentration), more frequent hunger cues leading to more frequent feeds (over-dilution), or more total ounces offered and consumed.[24-26,46]

Moreover, limited research has been conducted to determine if reconstituted infant formula provides twenty kilocalories per ounce, as intended.[46] In most cases, research comparing the growth of breastfed infants to formula-fed infants assumes that reconstituted infant formula is similar in caloric distribution (twenty kilocalories per ounce) compared to human breastmilk.[24,26,49-51] Although infant formula is designed to be as close in composition to human breastmilk as possible, the process of reconstituting infant formula leaves room for human error, which could affect the concentration of the infant formula bottles and overall infant intake.[52,53] In a recent study, Morais and colleagues[52] analyzed home-prepared bottles of infant formula and found that the composition of infant formula bottles was highly variable, placing infants at risk for nutritional inadequacies. The research group specifically found that reconstituted infant formula exceeded the requirements for energy, protein, and carbohydrates, while lacking adequate calories from fat.[52] Similarly, Renfrew and colleagues[53] published a review paper summarizing risks associated with infant formula preparation. The researchers found that among the five included studies, all detected inaccuracies in reconstitution of infant formula, with over-concentration being more common than under-concentration; however, both over-concentration and under-concentration occurred.[53] Therefore, observing maternal home-preparation of infant formula bottles would help to further explore the possibility that mothers may not be reconstituting infant formula according to the directions, regardless of intent. Furthermore, talking to mothers via in-depth interviews may help to explain the reasons behind some of these maternal behaviors and whether or not the behaviors are intentional.

Low-income population and maternal infant-feeding practices:

Low-income mothers in the US are at risk for infant-feeding behaviors which could lead to excessive rapid weight gain during the first year of life and subsequent overweight and obesity

in childhood.[37,54-56] For example, not only are low-income mothers more likely to formula feed, but they are also at risk for adding infant cereal to prepared bottles of infant formula and for early introduction of solid foods.[37,54,55] The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is an appropriate target population for this study because WIC is a federally-funded government assistance program serving over half of the infants born in the US, and one of the criteria for program eligibility is an annual household income less than 185% of the Federal Poverty Level.[57]

WIC provides a standard amount of infant formula per month, which is a sufficient amount of formula to meet infants' needs during the first month or two of life.[58,59] However, as infants grow larger, the standard amount supplied is eventually less than infants need for the entire month.[58,59] Since WIC is a supplemental nutrition program, caregivers are responsible for purchasing formula after this monthly supply is depleted.[59] This is of concern, as formula is more expensive than both infant cereal and solid foods, and supplementing formula feeds with these alternatives may seem to be the most logical and affordable option for low-income populations.[37] Engaging in more convenient and cost-effective behaviors can be tempting, especially if mothers are unaware of the potential long-term consequences of improper infant-feeding practices or if the recommended feeding behaviors are considered incongruent with "real world" needs.[37]

Mixed methods research:

Mixed methods research combines quantitative and qualitative research methods into a single study to answer the same research question(s).[60,61] This intentional integration of research methods has been highly valued and utilized by educational researchers for many years.[60] The justification for using a mixed methods study design resides in the fact that the quantitative and qualitative data can provide more complete results when combined, than provided by either

method alone.[60,61] The use of diverse study methodologies reflects the complex problems currently faced by public health researchers, such as health disparities and social determinants of health.[60,61] There is a growing acceptance of conducting mixed methods studies to help address these complex issues in the field of health sciences.[60,61] A common reason for using a mixed methods approach is to triangulate or validate data by testing the same research question using more than one methodology to see if different methodologies provide the same or similar results.[61]

A common considered fault of mixed methods studies is that they are sometimes in essence two separate studies with different research questions, inappropriately combined into a single study.[60] According to the National Institutes of Health, there are three ways to effectively integrate quantitative and qualitative data: merging data, connecting data, and embedding data.[61] Merging data occurs when researchers describe the quantitative data (numeric terms) and then describe how the qualitative data (textual or pictorial terms) supports or refutes the quantitative results.[61] Merging data can also occur when the qualitative data is transformed to numeric terms and then is compared to the quantitative data.[61] Connecting data occurs when one dataset (i.e., quantitative survey) informs the subsequent data collection (i.e., interview questions).[61] Embedding data occurs when a secondary dataset is embedded within the larger primary design.[61] Effectively integrating quantitative and qualitative data using one of these techniques could help to describe maternal infant-feeding practices and to explain the reasons behind observed maternal infant-feeding practices.

Implications for future research and practice:

There is limited evidence observing and describing infant formula preparation practices among low-income, formula-feeding mothers of very young infants.[62] Future research should

address this gap by further exploring maternal infant formula preparation practices and related maternal knowledge, attitudes, and beliefs pertaining to infant-feeding among this target population. A mixed methods approach would be an appropriate study design to produce both quantitative and qualitative descriptions of maternal infant-feeding practices, leading to a more complete understanding of the motivators behind maternal behavior. The targeted objective of the present study is to explore maternal infant formula preparation practices and related knowledge, attitudes, and beliefs, among low-income, formula-feeding mothers of very young infants. This greater understanding of maternal behaviors could help to achieve the overarching goal of implementing appropriately-designed, evidence-based public health interventions teaching mothers how to correctly prepare infant formula bottles according to recommendations, thereby decreasing the risk for negative health outcomes among formula-fed infants in the US.

CHAPTER II: MANUSCRIPT

Abstract

Background: The obesity epidemic in the United States (US) is a well-established public health crisis associated with immense national healthcare expenditures. The first two years of life represent a potentially critical intervention period for attenuation of inappropriate rapid weight gain and risk of subsequent overweight and obesity in childhood. Low-income mothers in the US are at risk for formula-feeding and early introduction of solid foods, which are behaviors that could lead to excessive rapid weight gain during this critical time period. However, little is known about actual, rather than self-reported, maternal infant-feeding behaviors related to proper infant formula preparation.

Objective: To explore maternal infant formula preparation practices and related knowledge, attitudes, and beliefs, among low-income, formula-feeding mothers of very young infants.

Methods: This study utilized a cross-sectional, mixed methods design. Participants were mothers of normal birth weight, healthy, term infants less than three months of age, who were predominantly formula-feeding with powdered or from-concentrate infant formula, and who were WIC income-eligible. Study activities included home observations of infant formula preparation and in-depth interviews. Descriptive statistics were used to describe the sample demographic characteristics and home-observation variables. Thematic analysis was used to identify themes present in the in-depth interviews. The mixed methods approach was used to triangulate results of both study activities.

Results/Conclusions: Behaviors including over-concentration, over-dilution, modifications/additions to prepared infant formula, and early introduction of solid foods (i.e., cereal added to bottles of infant formula) were observed during the home observations and/or were described during the in-depth interviews. Additionally, there appeared to be inconsistencies

between behaviors observed during formula preparation and those reported in subsequent in-depth interviews. Targeting knowledge and skills gaps along with motivators of maternal behaviors in this population could diminish the prevalence of infant-feeding practices that may predispose infants to inappropriate rapid weight gain.

Introduction

The first two years of life represent a potentially critical intervention period for attenuation of inappropriate rapid weight gain and subsequent overweight and obesity in childhood.[10-15] Following expert infant-feeding recommendations may be protective of excessive rapid weight gain early in life.[10-15] The World Health Organization recommends exclusively breastfeeding infants for the first six months of life and continuing breastfeeding up to two years of age.[21] Similarly, the American Academy of Pediatrics recommends exclusively breastfeeding infants for the first six months of life and continuing breastfeeding at least one year or as long as mutually desired by the mother and infant.[22]

Despite initiatives to increase breastfeeding initiation, duration, and exclusivity rates, most infants in the United States (US) are not fed according to these recommendations.[27] Some mothers are not able to breastfeed, choose not to breastfeed, or engage in early weaning practices for a variety of reasons.[29,30] US infants who are not breastfed exclusively during the first six months of life are predominantly offered infant formula as the primary or supplemental source of essential nutrients.[31] Thus, there is a need to explore infant-feeding behaviors among families who are unable to or choose not to breastfeed their infants according to recommendations, so that interventions can focus on decreasing potential excessive rapid weight gain among the large population of formula-fed infants in the US.

Behaviors such as adding infant cereal to prepared bottles of infant formula and early introduction of solid foods (i.e., infant cereal added to bottles of infant formula) contradict infant-feeding recommendations for formula-fed infants less than four months of age, and could lead to excessive rapid weight gain during the first year of life.[32-34] In addition, other practices, such as over-concentration, over-dilution, or too many ounces offered and consumed, may also

lead to excess caloric intake, and subsequent excessive rapid weight gain during the first year of life.[46,47] Although little research has been conducted regarding incorrect preparation of infant formula and later overweight/obesity,[46] the association is theoretically plausible due to the potential for excess caloric intake per ounce (over-concentration), more frequent hunger cues leading to more frequent feeds (over-dilution), or more total ounces offered and consumed.[24-26,46]

Low-income mothers in the US are at risk for infant-feeding behaviors, which could lead to excessive rapid weight gain during the first year of life and subsequent overweight and obesity in childhood.[37,54-56] Not only are low-income mothers more likely to formula feed, but they are also at risk for adding infant cereal to the bottle and for early introduction of solid foods.[37,54,55] The Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) is an appropriate target population for this study because WIC is a federally-funded government assistance program serving over half of the infants born in the US, and one of the criteria for program eligibility is an annual household income less than 185% of the Federal Poverty Level.[57]

There is limited evidence observing and describing infant formula preparation behaviors among low-income, formula-feeding mothers of very young infants.[62] Therefore, the objective of this study was to further explore maternal infant formula preparation practices and related knowledge, attitudes, and beliefs via a mixed methods study among low-income, formula-feeding mothers of infants less than three months old.

Research Methods

Study Design

This was a cross-sectional, mixed methods study design. Home observations of maternal infant formula preparation behaviors were completed using a checklist designed by the research

team. One-on-one, in-depth interviews assessing maternal knowledge, attitudes, and beliefs related to infant-feeding practices and behaviors were completed using a semi-structured interview guide. This study was approved by the University of Tennessee Institutional Review Board (IRB).

Eligibility and Recruitment

Eligible participants were mothers of normal birth weight, healthy, term infants less than 2.5 months of age at recruitment, who were predominantly formula-feeding (i.e., breastfeeding two or fewer times per day), using powdered or from-concentrate infant formula, and who were WIC income-eligible (based on 2012 – 2013 WIC eligibility guidelines).[63] Recruitment occurred via flyers posted at community health organizations serving the target population, as well as via online social media postings. Eligibility screening occurred over the phone or online, depending on how potential participants contacted the research lab. Eligible participants who completed the online screen were contacted via telephone, and study activities were explained at that time. Study activities took place in participants' homes, and two research assistants were present at each home visit. Upon completion of all study activities, participants were compensated with a twenty-dollar gift card to a national retail chain. Informed consent was obtained verbally over the telephone prior to the home visits, and written consent was obtained prior to commencement of study activities during the home visits.

Study Instruments

Infant Formula Preparation Checklist: The infant formula preparation checklist shown in **Figure 1** was designed by the research team to assess maternal behaviors related to appropriate and safe infant formula preparation such as hand washing, appropriate measuring techniques, and using correct formula to water ratios. Both research assistants observed and documented maternal

	Checklist	Notes
Environment	1. Location: ☐ Living Room ☐Kitchen ☐Bedroom ☐Other (note) 2. Distractions: ☐TV ☐Radio ☐Phone ☐Computer ☐People ☐None 3. Other people present: ☐No ☐ Yes (note) 4. Supplies from other room: ☐No ☐ Yes (note)	
Sanitation & Sterilization	1. Washed hands with soap and water: ☐No ☐Yes ☐Not Observed 2. Bottle equipment inspected: ☐No ☐Yes ☐Not Observed 3. Bottle washed with soap and water: ☐No ☐Yes ☐Not Observed a. If sponge/bottle brush used, disinfected: ☐No ☐Yes ☐N/A 4. Source of water: ☐Tap ☐Filtered ☐Bottled ☐Sterile baby water ☐Other (note) 5. Water boiled: ☐No ☐Yes 6. Bottle warmed: ☐No ☐Yes	
Formula Prep	1. In bottle first: ☐Water ☐Formula 2. Amount of water: ___ oz a. Water leveled: ☐Flat surface ☐At eye level ☐Quickly eyed ☐Already in bottle 3. Scoop from can used: ☐No (note) ☐Yes a. # of scoops: ___ b. Formula scoop: ☐Level ☐Unleveled c. Formula leveled: ☐Against can ☐Tapped ☐Used finger ☐N/A ☐Other (note) 4. Cereal in bottle: ☐No ☐Yes 5. Other additions to bottle: _____ 6. Shakes bottle: ☐No ☐Yes a. How long: _____ 7. More formula added: ☐No ☐Yes 8. More water added: ☐No ☐Yes	

Figure 1. Infant formula preparation checklist used for home-observations conducted among low-income, formula-feeding mothers

behaviors using identical checklists. Behaviors not specifically captured by the checklist, such as the state of the environment in which the formula preparation occurred, were recorded in the notes section.

Semi-structured Interview Guide: The interview guide was designed by members of the research team with expertise in infant-feeding (KK, JN), qualitative methods (LSG), and infant-feeding food safety practices (JB). Research assistants were trained in qualitative data collection and analysis methods by LSG. Interview questions inquired about topics such as the process of infant formula preparation, the timing for introduction of solid foods, the addition of infant cereal to bottles, infant cues, and sources of trusted infant-feeding information. For the full semi-structured interview guide, reference **Appendix E**. Interviewers were encouraged to probe further, when appropriate.

Study Activities

Home Observations of Infant Formula Preparation: At each home visit, participants were asked to prepare at least two infant formula bottles. First, they were asked to prepare a bottle as they normally would, using their own infant formula and equipment ('Bottle 1'). The purpose of Bottle 1 was to assess how participants normally prepared infant formula bottles. Prior to the home visit, participants were queried regarding the brand and type of infant formula they provided to their infants. After preparing Bottle 1, participants were asked to prepare a bottle using supplies provided by the research team, which included a brand and type of infant formula that was different from what each participant reported using prior to the home visit ('Bottle 2'). The purpose of Bottle 2 was to determine if participants prepared bottles differently and/or read the directions on the back of the formula container when presented with an unfamiliar brand/type of infant formula. After preparing Bottle 2, participants were asked if they ever prepared an

infant formula bottle differently than they prepared Bottle 1. If participants answered in the affirmative, they were asked to prepare a third bottle to demonstrate how they might prepare bottles differently ('Bottle 3'). The purpose of Bottle 3 was to assess other ways participants prepared infant formula bottles.

Semi-structured, In-depth Interviews: After completing the bottle-preparation activity, participants completed the in-depth interview. The first research assistant served as the interviewer and the second served as the note taker. Note takers were also responsible for writing up field notes immediately following the home visits. Interviews were audio-recorded.

Data Analysis

Immediately after each home visit, the two infant formula preparation checklists were compared and any discrepancies were discussed. A final master copy was then created using the agreed upon responses. For example, if an observer was distracted by a child and did not observe whether or not the formula scoop was leveled, then preference would be given to the observer who did observe this behavior. The master copy was subsequently coded and double-entered into an electronic spreadsheet. Descriptive statistics (means, frequencies, and standard deviations) were used to describe observed maternal behaviors.

For the in-depth interviews, audio-recordings were uploaded to a password-protected computer and backed up on a secure server. Recordings were then transcribed, verbatim, by trained research assistants using a transcription software program (InqScribe). Subsequently, six members of the research team (RE, JN, KB, ZL, KK, LSG) independently read, memoed, and summarized major themes present in each transcript. After each transcript was independently reviewed, the six research team members met to discuss identified themes, documenting the number of times each theme arose. This process was repeated for each transcript, with identified

and emergent themes being organized by frequency. The research team agreed that saturation was reached after the completion of ten in-depth interviews. Then, three additional interviews were conducted and analyzed, confirming saturation. Therefore, a total of thirteen interviews were completed.

Results

Participant Characteristics

Recruitment occurred from August 2012 until April 2013. A total of 143 potential participants were screened, with 120 (84%) of those screened being ineligible based on at least one exclusion criterion. Of those ineligible, the primary reasons for ineligibility included a reported infant age greater than 2.5 months at the time of recruitment (50%), breastfeeding greater than two times per day or offering ready-to-feed infant formula (28%), and/or a reported annual household income greater than 185% of the Federal Poverty Level (24%). Of the twenty-three potential participants who were eligible for the study, thirteen participants completed all study activities. Participant demographic characteristics are summarized in **Table 1**. Participants were generally in their mid-twenties, with infants about two months of age who were of normal birth weight (an inclusion criterion), and the majority reported being single. Furthermore, the majority of the sample reported being White or Caucasian, reported that they had initiated breastfeeding, and reported that they had more than one child. Slightly less than half of the sample reported completing some college.

Infant Formula Preparation Observations

Table 2 describes results of observations of bottle-preparation behaviors. Twelve participants prepared a bottle using their own supplies (‘Bottle 1’); one participant was unable to do so secondary to not having her own supplies at the time of the home visit. All participants

Table 1. Demographic characteristics of a sample of low-income, formula-feeding mothers of infants less than three months old

Variable (n=13)	Mean	Standard Deviation
Maternal Age, years	27	7.6
Infant Age, weeks	8.7	3.59
Infant Birth Weight, grams	3240	372.5
	Frequency % (n)	
Infant Gender Percent Male	31 (4)	
Maternal Race White/Caucasian Other	61 (8) 39 (5)	
Maternal Education Level Middle or High School Some College/College	54 (7) 46 (6)	
Maternal Employment Status Percent Working	31 (4)	
Maternal Marital Status Single Married/Cohabitating	62 (8) 38 (5)	
Percent Primiparous	31 (4)	
Percent Initiating Breastfeeding	54 (7)	

Table 2. Results of home observations of prepared bottles of infant formula

Variable	% performing behavior (n)	
	'Bottle 1' Maternal Supplies (n=12)	'Bottle 2' Research Team-Provided Supplies (n=13)
Observed reading instructions on formula container	--	46 (6)
Observed adding water to bottle before powdered formula added	75 (9)	69 (9)
Observed use of correct water to formula ratio	92 (11)	77 (10)
Observed leveling formula in scoop	58 (7)	69 (9)
Observed adding infant cereal to bottle	25 (3)	15 (2)
Observed adding other ingredients to bottle	8 (1)	0 (0)

prepared a bottle using the infant formula and equipment provided by the research team ('Bottle 2'). Only one participant reported, during the observation, that she sometimes prepared an infant formula bottle differently than Bottle 1. However, in order to avoid violating the confidentiality of the study protocol approved by the IRB, these data are not included in **Table 2**.

As shown in **Table 2**, when the infant formula was provided by the research team (an unfamiliar powdered infant formula), less than half of the participants (46%) looked at the instructions on the back of the formula container. Nearly 75% of participants (n=9) prepared the bottle by adding water to the bottle before adding the powdered formula, as described in the instructions. The majority of participants attempted to level the scoop of powdered formula by either tapping the scoop against the formula container or scraping the top of the scoop against the side of the container. Despite these efforts, the powder was not always observed as being "level" by the research assistants (data not shown). When preparing Bottle 1, nearly all participants used the correct water to formula ratio (one scoop of powder per two ounces of water). However, fewer participants used the correct ratio when preparing Bottle 2. One participant reported intentionally over-diluting the bottle when preparing the unfamiliar formula, stating that she does this whenever using a new formula in order to assess her infant's liking of the novel flavor before making it to the recommended strength. Three participants added infant cereal to Bottle 1, and two participants added infant cereal to Bottle 2. The amounts of infant cereal added appeared to vary, and different sized measuring spoons were used. For some bottles, the infant cereal was added prior to adding the infant formula. One participant added corn syrup to Bottle 1 ('usual bottle') as instructed by her physician to help with infant constipation.

Additional Observations

No participants were observed washing their hands or washing the bottles prior to preparing the infant formula. For most participants, there were many distractions when preparing the infant formula bottles. Distractions included other people in the room and noise from the television, electric appliances, and handheld electronic devices. Infant formula bottles were prepared in numerous locations including in the kitchen, living room, bathroom, bedroom, and on the porch. No participants were observed boiling the water that they used to prepare the infant formula bottles; however, some participants reported boiling water previously and then storing it in containers for later use. Participants used many different sources of water including tap water, filtered tap water, bottled water, well water, and sterile nursery water. For the tap water, multiple participants used hot tap water, and one participant reported microwaving the tap water she uses to prepare infant formula bottles. Additionally, one participant warmed Bottle 1 using a bottle warmer. This instance was the only observed use of a bottle warmer. None of the participants leveled the water on a flat surface and at eye level. All participants used the scoop provided in the relevant formula container for measuring the infant formula. Two participants added more water to Bottle 1 after shaking and assessing the volume. This was done in order increase the total volume to the desired measurement line on the formula bottle. For example, if the participant wanted to prepare eight ounces of infant formula, but the prepared amount did not reach the eight-ounce measurement line on the bottle, she then added water until this desired volume was reached.

Themes Emerging from In-depth Interviews

From the in-depth interviews, four major themes emerged and are organized below, in descending order, by magnitude. Selected quotes supporting each theme are summarized in **Table 3**.

Preparing Infant Formula is Not Common Sense:

All but one participant reported feeling nervous when preparing an infant formula bottle for the very first time. However, participants said they felt more comfortable preparing infant formula bottles as they continued to gain more experience. Participants reported valuing advice more when it came from another parent (i.e., healthcare provider, peer, family member, stranger) as opposed to when the advice came from a non-parent. Advice from healthcare providers was highly valued. Rather than learning how to prepare infant formula in a formal setting, many participants reported learning from their own past experiences or by observing others.

Misperceptions About Formula:

Participants communicated varying perceptions about infant formula. Some believed that infant formula was not enough to keep an infant full and content, and others believed that infant formula contains everything an infant needs to be healthy and grow appropriately. Additionally, almost all participants believed infant formula was a sterile compound, and thought that boiling the water was only recommended to eliminate bacteria in the water, not the formula. Some participants reported understanding the importance of the exact water to formula ratio, but then supported the addition of infant cereal and/or other foods to the bottle. Furthermore, participants generally had less of a problem with over-concentration of infant formula, compared to under-concentration, as they considered over-concentration more of a taste and consistency problem as

Table 3. Outline of major themes and supporting quotes from qualitative interviews with low-income, formula-feeding mothers

Major Theme	Supporting Quotes
Preparing Infant Formula is Not Common Sense	*"The very first time I made a bottle…. I did worry a lot and stuff you know whether or not if the baby was gettin' the right amount of stuff and everything, and I still do sometimes because I don't see how all that works…." [referring to the formula to water ratio]* *"I just wait for when the doctors tell me to." [explaining trusted source of health information]*
Misperceptions About Formula	*"We gave her two scoops to eight ounces to begin with to make sure that she liked it and then once we figured out she was good with it we started giving her four scoops." [describing the reasoning for altering formula to water ratio]* *"I don't put like extra, a lot of extra in there but if it's not a complete level scoop or it's just a little over the ten ounces, I know it's okay." [referring to the formula to water ratio]*
Cost and Convenience Motivate Maternal Behaviors	*"I've learned not to waste any milk and milk is expensive too and you're always running out of cans." [cost]* *"If you make it all at one time it's like wasting milk…and some people can't afford milk." [cost]* *"I remember waking up in the middle of the night, three or four times in the night, making a lot of bottles. My granny tell me girl if you don't put some cereal in that baby's bottle. Put some cereal in his bottle and changed my life." [convenience]*
Maternal Interpretation of Infant Cues Overrides Expert Recommendations	*"It's [formula] not enough!...I go through less bottles putting cereal in my bottles than I do with no cereal, and they sleep way longer, you not making as many bottles that you would be with just the regular milk. I've tried to go by the rules, and I've learned that two weeks, it's time for some cereal." [explaining why infant formula is not enough for a young infant]* *"We watch her belly cause…when she eats like the whole bottle you can tell when she's getting full or not; her belly gets really huge. We just watch her belly usually nothing else." [not using earlier satiety cues]* *"When his tummy starts rumblin', he's full." [not using earlier satiety cues]*

opposed to a potential health threat for the infant. Most participants did not agree with under-concentration; however, some of the same participants who did not agree with under-concentrating infant formula reported using incorrect water to formula ratios, resulting in an under-concentrated bottle. With regards to infant cereal, there appeared to be a belief that infant formula and infant cereal were similar in composition, and infant cereal was described as convenient and cost-efficient (as compared to infant formula).

Cost and Convenience Motivate Maternal Behaviors:

Participants reported being highly motivated by cost and convenience. Infant-feeding behaviors appeared to be influenced by the perceived cost and convenience of the given behavior. For example, participants reported using different volumes of infant formula or adding infant cereal to formula bottles in order to modify infant sleep behaviors. On many occasions, participants described infant formula as being very expensive when explaining the reasons for their infant-feeding behaviors.

Maternal Interpretation of Infant Cues Overrides Expert Recommendations:

Participants reported attending to infant needs by interpreting infant cues; however, there appeared to be discrepancies between maternal reported infant cues and the associated reported maternal responses. Some participants communicated that they did not follow the general recommendations given because their baby was different from most babies. For the most part, participants reported deviating from the normal guidelines as long as they did not perceive their behaviors as being harmful to their infants.

Discussion

The results of this study not only indicate that bottle preparation behaviors that could contribute to inappropriate rapid weight gain are occurring among low-income, formula-feeding

mothers of very young infants, but also describe some potential motivators for the observed maternal behaviors. These behaviors, including over-concentration and/or over-dilution of infant formula, excessive ounces of formula offered and consumed, modifications/additions to prepared infant formula, and early introduction of solid foods were observed and/or reported among this sample of low-income, formula-feeding mothers of very young infants. However, it is important to note that although these results describe a population of low-income mothers, literature suggests that similar behaviors may be present among higher income mothers as well.[52]

The qualitative findings from this study support previous literature that states that behaviors such as adding cereal to bottles or providing larger bottles are thought to induce and extend infant sleep and are behaviors potentially motivated by maternal convenience and financial concerns.[35-38,59] Since WIC is a supplemental nutrition program, caregivers are responsible for purchasing formula after the monthly supply is depleted.[59] This is of concern, as formula is much more expensive than both infant cereal and typical solid foods marketed to mothers of young infants, and supplementing formula feeds with these alternatives may seem to be the most logical and affordable option for low-income populations.[59] However, these behaviors contradict expert infant-feeding recommendations.[32-34] If mothers are unaware of the potential long-term consequences of improper infant-feeding behaviors or if the recommended practices are considered incongruent with "real world" needs, the perceived convenience and cost-effectiveness of these behaviors will likely weigh more heavily in the decision-making process.[37] Furthermore, as supported by this study and others,[64] mothers may be engaging in bottle-preparation behaviors that deviate from expert recommendations due to the misinterpretation of infant cues and subsequent mismatched responses to these cues.

Additionally, the present study demonstrated potential discrepancies between observed and reported maternal bottle-preparation practices. It is important to note that, regardless of intent, mothers contradicted themselves many times when describing their own knowledge, attitudes, and beliefs related to bottle-preparation practices. Also, regardless of intent, observed maternal behaviors often deviated from the behaviors reported in the in-depth interviews. Therefore, it should not be assumed that reported maternal behaviors are always congruent with actual behaviors. Determining the reasons for these discrepancies was outside of the scope of this project; however, other literature suggests that mothers may have a false sense of confidence related to food safety and infant-feeding practices.[65] Additionally, the observed discrepancies could have been related to socially desirable responses rather than reflecting actual differences in reported and observed behaviors. However, results of this study indicate that relying on only maternal report of bottle-preparation behaviors may result in collection of incomplete data. Future research should include strategies allowing for further observation of infant formula preparation behaviors among low-income, formula-feeding mothers of very young infants.

Study Strengths and Limitations

A major strength of this study is the use of a mixed methods approach, which produced both quantitative and qualitative descriptions of maternal bottle-preparation practices. The infant formula preparation observations provided quantitative description of in-home maternal infant formula preparation behaviors, while the in-depth interviews resulted in rich textual data explaining some of the observed maternal behaviors. Using a mixed methods study design can provide more complete results than those obtained by individual methods.[60,61] A common reason for using a mixed methods approach is to triangulate or validate data by testing the same research question using more than one methodology to see if different methodologies provide the same or

similar results.[61] For example, in the present study, improper infant formula preparation behaviors were not only observed by researchers, but were also described by the participants, further validating the study finding that these behaviors are prevalent among the study population.

Study limitations include the cross-sectional nature of the study, as behaviors of interest may have occurred prior to or following each home visit, but were not observed during the actual observation period. A longitudinal study, using more intensive observational methodology, may capture a greater variety of behaviors. Additionally, the small sample size of this study limits the generalizability of the findings, and future research should explore these research questions among larger sample sizes. Finally, it is likely that some degree of bias was present, in that it is possible that the observations and reported behaviors were influenced by the participants' desire to report or practice socially acceptable behaviors, which could vary from their normal behaviors. Future research should employ novel methodologies to assist in reducing this bias.

Implications for Future Research and Practice

Further research is needed to better understand maternal infant formula preparation behaviors that differ from recommendations, especially among low-income, formula-feeding mothers in the US. In the interim, healthcare providers should not assume that infant formula is being prepared according to recommendations at home. Targeting the gaps in knowledge and skills along with the motivators of maternal behavior, described in this study and others, will be essential to diminish the prevalence of maternal infant-feeding practices that differ from recommendations among this target population. In addition, though breastfeeding is recognized as the gold standard in infant-feeding, healthcare providers must delicately balance support for breastfeeding with the needs of formula-feeding mothers and their infants. Ultimately,

supporting proper infant formula preparation behaviors may lead to positive short-term and long-term health outcomes for formula-fed infants in the US, thereby decreasing associated national healthcare expenditures.

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CHAPTER III: EXPANDED METHODS

Study Design

This was a cross-sectional, mixed methods study design. Home observations of maternal infant formula preparation behaviors were completed using a checklist designed by the research team. One-on-one, in-depth interviews assessing maternal knowledge, attitudes, and beliefs related to infant-feeding practices and behaviors were completed using a semi-structured interview guide. This study was approved by the University of Tennessee Institutional Review Board. Additionally, this study was Phase II of a larger project and was designed in part based on findings from Phase I of the larger project. A brief summary of Phase I study activities is provided below.

Phase I Methodology

Similar to Phase II, eligible participants for Phase I were WIC-eligible, formula-feeding mothers (greater than sixteen years of age) with healthy infants less than three months old. During Phase I, the research team collected infant formula samples for a twenty-four hour period at two different time points (about two months of age and about four months of age). At each time point, infant weight, length, and head circumference were measured by trained research staff. In addition, participants completed infant intake forms for forty-eight hours (samples collected for the last twenty-four hours) at both time points to assess the amount of formula offered to the infant, amount leftover after feeding, whether or not cereal was added to the bottle, how much cereal was added (if any), amount of spit-up (if any), and who fed the infant the bottle. The intake forms also accounted for calories obtained from other sources, such as juice or solid foods, and how many hours the infant was sleeping in between feeds. The participants also completed a detailed questionnaire about infant-feeding behaviors and beliefs at both time points. A total of fifty-four participants completed all study activities for Phase I.

Expert Training in Qualitative Research and Data Collection

Phase II planning began with a two-day training in August 2012 led by qualitative research expert, Dr. Suzie Goodell. All research assistants currently working on the project attended the training. The first day was spent learning best practices for conducting focus groups and one-on-one, in-depth interviews. The second day was primarily devoted to the development of the semi-structured interview guide. During the following weeks, the semi-structured interview guide was finalized, and research assistants practiced interviewing skills by conducting audio-recorded practice phone interviews with mothers. A total of eight practice phone interviews were completed.

Participant Recruitment and Eligibility

Recruitment occurred from August 2012 until April 2013. Eligible participants were mothers (greater than sixteen years of age) of normal birth weight, healthy, term infants less than 2.5 months of age at recruitment, who were predominantly formula-feeding (i.e., breastfeeding two or fewer times per day), using powdered or from-concentrate infant formula, and who were WIC income-eligible (based on 2012 – 2013 WIC eligibility guidelines).[63] The prescreening tool used to determine eligibility can be found in **Appendix A**. Recruitment occurred via flyers (**Appendix B**) posted at community health organizations serving the target population, as well as via online social media postings. Online social media postings included Facebook, Twitter, and craigslist.

Screening Potential Participants and Method of Obtaining Informed Consent

Potential participants who contacted the Infant, Child, and Adolescent Nutrition (ICAN) Lab at The University of Tennessee, Department of Nutrition, either via online prescreen

(Survey Monkey platform) or direct phone call to the lab, were screened for eligibility (determined using criteria described above and in **Appendix A**). Prior to obtaining sensitive or identifying information (mother's name, phone number, email, and mailing address) potential participants were asked only those questions used to determine eligibility (maternal and infant date of birth, participation in WIC or the Supplemental Nutrition Assistance Program (SNAP, formerly the Food Stamp Program), infant birth weight, infant-feeding mode, infant health issues, and maternal zip code). Eligibility could be determined over the telephone for those who completed this prescreen by phone. Research assistants reviewed the online prescreens and contact information to verify infant/maternal age and location of residence in order to confirm eligibility. Those who completed the online prescreen and were ineligible for the study were contacted either by phone or email (depending on given maternal preference) to notify them of ineligibility and thanking them for their interest and time. Those who completed the online prescreen and were eligible for the study were contacted via telephone to further explain study activities.

Upon determination of eligibility, study activities (see below) were described and participants were asked if they would like to participate in the study (**Appendix C**). If an individual was not interested in participating, the research team asked the individual to explain, if they so desired, the reasons for disinterest. For those interested in completing the study, upon obtaining initial verbal consent, contact information (mother's name, phone number, email, and mailing address) was collected, if not already collected via the online screen, and home visits were scheduled. Also, during this phone call, the research assistants inquired about the current brand/type of infant formula currently being used. Regardless of eligibility status, or subsequent participation in this study, data from the prescreens were maintained for use in aggregate reports.

Upon determination of eligibility, a brief explanation of study activities, and expression of interest, one copy of the Phase II Consent Form (**Appendix D**) was mailed to the potential participants. They were instructed to keep this copy of the form for their personal records. Another copy of the consent form was signed by the participants during the home visits prior to the commencement of study activities (described in detail below). The signed forms were stored in a locked office of the Jessie Harris Building (213-A).

Study Instruments

Infant Formula Preparation Checklist: The Infant Formula Preparation checklist (**Appendix E**) was designed by the research team to assess maternal behaviors related to appropriate and safe infant formula preparation such as hand washing, appropriate measuring techniques, and using correct formula to water ratios. Behaviors not specifically captured by the checklist, such as the state of the environment in which the formula preparation occurred, were recorded in a notes section.

Semi-structured Interview Guide: The interview guide was designed by members of the research team with expertise in infant-feeding (KK, JN), qualitative methods (LSG), and infant-feeding food safety practices (JB). Research assistants were trained in qualitative data collection and analysis methods by LSG, as previously described. The semi-structured interview guide can be found after the infant formula preparation checklist in **Appendix E**. Interviewers were encouraged to probe further, when appropriate.

Study Activities

Home Observations of Infant Formula Preparation: At each home visit, participants were asked to prepare at least two infant formula bottles (described below), and two research assistants observed and documented maternal behaviors using identical checklists. First, participants were

asked to prepare a bottle as they normally would, using their own infant formula and equipment ('Bottle 1'). The purpose of Bottle 1 was to assess how participants normally prepared infant formula bottles. After preparing Bottle 1, participants were asked to prepare a bottle using supplies provided by the research team, which included a brand and type of infant formula that was different from what each participant reported using prior to the home visit ('Bottle 2'). The purpose of Bottle 2 was to determine if participants prepared bottles differently and/or read the directions on the back of the formula container when presented with an unfamiliar brand/type of infant formula. After preparing Bottle 2, participants were asked if they ever prepared an infant formula bottle differently than they prepared Bottle 1. If participants answered in the affirmative, they were asked to prepare a third bottle to demonstrate how they might prepare bottles differently ('Bottle 3'). The purpose of Bottle 3 was to assess other ways participants prepared infant formula bottles.

Semi-structured, In-depth Interviews: After completing the bottle-preparation activity, participants completed the in-depth interview. The first research assistant served as the interviewer and the second served as the note taker. Note takers were also responsible for writing up field notes immediately following the home visits. An example of the field notes recorded can be found in **Appendix F**. Interviews were audio-recorded.

Participant Compensation: Each participant received twenty dollars in gift cards to a local retailer as compensation for completing study activities. Following each home visit, participants were mailed a copy of the "Making Safe Formula" flyer found in **Appendix G**, which describes the appropriate way to prepare infant formula.

Data Analysis

Immediately after each home visit, the two infant formula preparation checklists were compared and any discrepancies were discussed. A final master copy was then created using the agreed upon responses. For example, if an observer was distracted by a child and did not observe whether or not the formula scoop was leveled, then preference would be given to the observer who did observe this maternal behavior. The master copy was subsequently coded and double-entered into an electronic spreadsheet. Descriptive statistics (means, frequencies, and standard deviations) were used to describe observed maternal behaviors. SPSS Statistics (version 22) was used to calculate descriptive statistics for each variable.

For the in-depth interviews, audio-recordings were uploaded to a password-protected computer and backed up on a secure server. Recordings were then transcribed, verbatim, by trained research assistants using a transcription software program (InqScribe). A second research assistant reviewed each transcript for accuracy. Then, six members of the research team (RE, JN, KB, ZL, KK, LSG,) independently read, memoed, and summarized major themes present in each transcript. After each transcript was independently reviewed, the six research team members met to discuss identified themes, documenting the number of times each theme arose. This process was repeated for each transcript, with identified and emergent themes being organized by frequency. The research team agreed that saturation was reached after the completion of ten in-depth interviews. Then, three additional interviews were conducted and analyzed, confirming saturation. Therefore, a total of thirteen interviews were completed.

REFERENCES

1. Cali AM, Caprio S. Obesity in children and adolescents. *J Clin Endocrinol Metab.* 2008;93:31S-36S.

2. Ogden CL, Carroll MD, Curtin LR, et al. Prevalence of overweight and obesity in the United States, 1999-2004. *J Am Med Assoc.* 2006;295:1549-1555.

3. Francischetti EA, Genelhu VA. Obesity-hypertension: an ongoing pandemic. *Int J Clin Pract.* 2007;61:269-280.

4. Oldridge NB. Economic burden of physical inactivity: healthcare costs associated with cardiovascular disease. *Eur J Cardiovasc Prev Rehabil.* 2008;15:130-139.

5. Centers for Disease Control and Prevention. Overweight and Obesity: Facts. October, 2014. http://www.cdc.gov/obesity/data/facts.html.

6. Avery A, Bostock L, McCullough F. A systematic review investigating interventions that can help reduce consumption of sugar-sweetened beverages in children leading to changes in body fatness. *J Hum Nutr Diet.* 2014. DOI: 10.1111/jhn.12267.

7. Rush E, Simmons D. Physical activity in children: prevention of obesity and type 2 diabetes. *Med Sport Sci.* 2014;60:113-121.

8. Havas S, Aronne LJ, Woodworth KA. The problem of obesity in the United States has become increasingly prominent and is now recognized as a critical target for public health intervention. Introduction. *Am J Med.* 2009;122:1S-3S.

9. Johnston LM, Matteson CL, Finegood DT. Systems science and obesity policy: a novel framework for analyzing and rethinking population-level planning. *Am J Public Health.* 2014;104:1270-1278.

10. Stettler N, Zemel BS, Kumanyika S, et al. Infant weight gain and childhood overweight status in a multicenter, cohort study. *Pediatrics.* 2002;109:194-199.

11. Sacco MR, de Castro NP, Euclydes VL, et al. Birth weight, rapid weight gain in infancy and markers of overweight and obesity in childhood. *Eur J Clin Nutr.* 2013;67:1147-1153.

12. Birch LL, Anzman-Frasca S, Paul IM. Starting early: obesity prevention during infancy. Nestle Nutrition Institute workshop series. 2012;73:81-94.

13. Howe LD, Chaturvedi N, Lawlor DA, et al. Rapid increases in infant adiposity and overweight/obesity in childhood are associated with higher central and brachial blood pressure in early adulthood. *J Hypertens.* 2014;32:1789-1796.

14. Imai CM, Gunnarsdottir I, Thorisdottir B, et al. Associations between infant feeding practice prior to six months and body mass index at six years of age. *Nutrients.* 2014;6:1608-1617.

15. Gaffney KF, Kitsantas P, Brito A, et al. Baby steps in the prevention of childhood obesity: IOM guidelines for pediatric practice. *J Pediatr Nurs.* 2014;29:108-113.

16. Whitaker RC, Wright JA, Pepe MS, et al. Predicting obesity in young adulthood from childhood and parental obesity. *N Engl J Med.* 1997;337:869-873.

17. Eriksson JG, Forsen T, Tuomilehto J, et al. Early adiposity rebound in childhood and risk of Type 2 diabetes in adult life. *Diabetologia.* 2003;46:190-194.

18. Freedman DS, Khan LK, Dietz WH, et al. Relationship of childhood obesity to coronary heart disease risk factors in adulthood: the Bogalusa Heart Study. *Pediatrics.* 2001;108:712-718.

19. Ong KK, Ahmed ML, Emmett PM, et al. Association between postnatal catch-up growth and obesity in childhood: prospective cohort study. *Br Med J.* 2000;320:967-971.

20. James DC, Lessen R. Position of the American Dietetic Association: promoting and supporting breastfeeding. *J Am Diet Assoc.* 2009;109:1926-1942.

21. World Health Organization. Facts for Life. 4th ed. 2010.

22. Eidelman AI, Schanler RJ, Johnston M, et al. Breastfeeding and the Use of Human Milk. *Pediatrics.* 2012;129:827-841.

23. Heinig MJ, Nommsen LA, Peerson JM, et al. Intake and growth of breast-fed and formula-fed infants in relation to the timing of introduction of complementary foods: the DARLING study. *Acta Paediatr.* 1993;82:999-1006.

24. Li R, Magadia J, Fein SB, et al. Risk of bottle-feeding for rapid weight gain during the first year of life. *Arch Pediatr Adolesc Med.* 2012;166:431-436.

25. Hodges EA, Johnson SL, Hughes SO, et al. Development of the responsiveness to child feeding cues scale. *Appetite.* 2013;65:210-219.

26. Li R, Fein SB, Grummer-Strawn LM. Association of breastfeeding intensity and bottle-emptying behaviors at early infancy with infants' risk for excess weight at late infancy. *Pediatrics.* 2008;122::77S-84S.

27. Centers for Disease Control and Prevention. Breastfeeding Report Card, United States. 2014. http://www.cdc.gov/breastfeeding/data/reportcard.htm. Accessed 12-15-14.

28. Healthy People 2020. https://www.healthypeople.gov/. Accessed 12-15-14.

29. Li R, Fein SB, Chen J, et al. Why mothers stop breastfeeding: mothers' self-reported reasons for stopping during the first year. *Pediatrics.* 2008;69S-76S.

30. Brown CR, Dodds L, Legge A, et al. Factors influencing the reasons why mothers stop breastfeeding. *Can J Public Health.* 2014;105:e179-185.

31. Grummer-Strawn LM, Scanlon KS, Fein SB. Infant feeding and feeding transitions during the first year of life. *Pediatrics.* 2008;36S-42S.

32. East Tennessee Children's Hospital Infant Feeding Guidelines. 2005.

33. AAP Committee on Nutrition. *Pediatric Nutrition Handbook.* Kleinman R. (Ed). 6th Edition; 2009.

34. Weng SF, Redsell SA, Swift JA, et al. Systematic review and meta-analyses of risk factors for childhood overweight identifiable during infancy. *Arch Dis Child.* 2012;97:1019-1026.

35. Cubero J, Chanclon B, Sanchez S, et al. Improving the quality of infant sleep through the inclusion at supper of cereals enriched with tryptophan, adenosine-5'-phosphate, and uridine-5'-phosphate. *Nutr Neurosci.* 2009;12:272-280.

36. Crocetti M, Dudas R, Krugman S. Parental beliefs and practices regarding early introduction of solid foods to their children. *Clin Pediatr.* 2004;43:541-547.

37. Heinig MJ, Follett JR, Ishii KD, et al. Barriers to compliance with infant-feeding recommendations among low-income women. *J Hum Lact.* 2006;22:27-38.

38. Horvath A, Dziechciarz P, Szajewska H. The effect of thickened-feed interventions on gastroesophageal reflux in infants: systematic review and meta-analysis of randomized, controlled trials. *Pediatrics.* 2008;122:e1268-1277.

39. Vandenplas Y, Rudolph CD, Lorenzo CD, et al. Pediatric gastroesophageal reflux clinical practice guidelines: joint recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN) and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN). *J Pediatr Gastroenterol Nutr.* 2009;49:498–547.

40. Harris R, Nicoll AD, Adair PM, et al. Risk factors for dental caries in young children: a systematic review of the literature. *Community Dent Health.* 2004;21:71-85.
41. Norris JM, Barriga K, Klingensmith G, et al. Timing of initial cereal exposure in infancy and risk of islet autoimmunity. *J Am Med Assoc.* 2003;290:1713-1720.
42. Carletti C, Cattaneo A. Home preparation of powdered infant formula: is it safe? *Acta Paediatr.* 2008;97:1131-1132.
43. Richards GM, Gurtler JB, Beuchat LR. Survival and growth of Enterobacter sakazakii in infant rice cereal reconstituted with water, milk, liquid infant formula, or apple juice. *J Appl Microbiol.* 2005;99:844-850.
44. Poole JA, Barriga K, Leung DY, et al. Timing of initial exposure to cereal grains and the risk of wheat allergy. *Pediatrics.* 2006;117:2175-2182.
45. Ziegler AG, Schmid S, Huber D, et al. Early infant feeding and risk of developing type 1 diabetes-associated autoantibodies. *J Am Med Assoc.* 2003;290:1721-1728.
46. Fomon SJ, Filer LJ, Jr., Thomas LN, et al. Relationship between formula concentration and rate of growth of normal infants. *J Nutr.* 1969;98:241-254.
47. Fomon SJ, Filmer LJ, Jr., Thomas LN, et al. Influence of formula concentration on caloric intake and growth of normal infants. *Acta Paediatr Scand.* 1975;64:172-181.
48. Jeon GW, Jung YJ, Koh SY, et al. Preterm infants fed nutrient-enriched formula until 6 months show improved growth and development. *Pediatrics International.* 2011;53:683-688.
49. Dewey KG, Heinig MJ, Nommsen LA, et al. Breast-fed infants are leaner than formula-fed infants at 1 y of age: the DARLING study. *Am J Clin Nutr.* 1993;57:140-145.
50. Thompson AL. Intergenerational impact of maternal obesity and postnatal feeding practices on pediatric obesity. *Nutr Rev.* 2013;55S-61S.
51. Huh SY, Rifas-Shiman SL, Taveras EM, et al. Timing of solid food introduction and risk of obesity in preschool-aged children. *Pediatrics.* 2011;127:e544-551.
52. Penna de Carvalho MF, Morais TB, Batista de Morais M. Home-made feeding bottles have inadequacies in their nutritional composition regardless of socioeconomic class. *J Trop Pediatr.* 2013;59:286-291.
53. Renfrew MJ, Ansell P, Macleod KL. Formula feed preparation: helping reduce the risks; a systematic review. *Arch Dis Child.* 2003;88:855-858.
54. Yin HS, Sanders LM, Rothman RL, et al. Parent health literacy and "obesogenic" feeding and physical activity-related infant care behaviors. *J Pediatr.* 2014;164:577-583.
55. Thompson AL, Bentley ME. The critical period of infant feeding for the development of early disparities in obesity. *Soc Sci Med.* 2013;97:288-296.
56. Oliveira V, Racine E, Olmsted J, et al. The WIC program: background, trends, and issues food assistance and nutrition research report. 2002. www.ers.usda.gov/media/327957/fanrr27_1_.pdf. Accessed 02-19-13.
57. The United States Department of Agriculture. About WIC- WIC at a Glance. 2013. http://www.fns.usda.gov/wic/about-wic-wic-glance. Accessed 09-22-14.
58. The United States Department of Agriculture. WIC Food Packages Maximum Monthy Allowances. 2012. http://www.fns.usda.gov/wic/benefitsandservices/foodpkgallowances.HTM. Accessed 05-02-13.

59. Fornasaro-Donahue VM, Tovar A, Sebelia L, et al. Increasing breastfeeding in WIC participants: cost of formula as a motivator. *J Nutr Educ Behav.* 2014. DOI: http://dx.doi.org/10.1016/j.jneb.2014.03.003.

60. Yin RK. Mixed methods research: are the methods genuinely integrated or merely parallel? *Res Sch.* 2006;13:41-47.

61. Meissner HI, Creswell JW, Klassen AC, et al. *Best practices for mixed methods research in the health sciences.* United States Department of Health and Human Services, National Institutes of Health, Office of Behavioral and Social Sciences Research. 2011. http://obssr.od.nih.gov/mixed_methods_research/pdf/Best_Practices_for_Mixed_Methods_Research.pdf. Accessed 09-29-14.

62. Birch LL, Doub AE. Learning to eat: birth to age 2 y. *Am J Clin Nutr.* 2014;99:723S-728S.

63. The United States Department of Agriculture. Women, Infants and Children (WIC): WIC income eligibility guidelines. http://www.fns.usda.gov/wic/wic-income-eligibility-guidelines. Accessed 09-28-14.

64. Waller JH, Bower K, Spence ML, et al. Using grounded theory methodology to conceptualize the mother-infant communication dynamic: potential application to compliance with infant-feeding recommendations. *Matern Child Nutr.* 2013. DOI: 10.1111/mcn.12056.

65. Meysenburg R, Albrecht JA, Litchfield R, et al. Food safety knowledge, practices and beliefs of primary food preparers in families with young children. A mixed methods study. *Appetite.* 2014;73:121-131.

APPENDICES

Appendix A: Prescreening Form

Date: _____Screener Initials: _____ or □ Online Form

1. How did you hear about our study? _____
2. What ZIP code do you live in? _____
3. What is your date of birth? ____/_____/____ ☐
   mm dd yyyy
4. Do you have a baby or are you expecting?
   □ Baby (0) □ Pregnant (1) → What is your due date? ____/____/____
   mm dd yyyy

If "PREGNANT", skip to question 12

5. What is your baby's birth date? ___/____/____
   mm dd yyyy

   6a. Age of baby in days/months: _____ (Screener calculates)

   6b. Is baby > 3 months (91 days) old? □ No (0) □ Yes (1) ☐

   EXCLUSION CRITERION: ***If YES, check box***

6. Is your baby a boy or a girl? □ M (0) □ F (1)

7. How much did your baby weigh at birth? _____lbs, _____oz. (_____kg, _____g)

   8a. Was infant >/= 5 lbs, 8oz at birth? (2.5 kg or 2500 g) □ No (0) □ Yes (1)

   EXCLUSION CRITERION: ***If NO, check box*** ☐

8. Does your baby have, or has he/she had any chronic health conditions since birth? (prompt to parent: "such as kidney problems, heart problems, etc.")
   □ No (0) HEALTHY □ Yes (1) ☐

   EXCLUSION CRITERION: ***If YES, check box***

9. Is your baby currently breastfeeding or using formula, or both?

□ Formula only (0) □ Breastfeeding only (1) □ Both (2)

□ Neither (3)

If "Both", ask: 10a. How many times do you nurse a day? _____ ☐

EXCLUSION CRITERION: ***If > 2/day, check box***

10. If offering formula:

Are you using powdered, from-concentrate, or ready-to-feed formula?

□ Powdered (0) □ From-concentrate (1) □ Ready-to-feed (2) □ Not offering formula (3)

EXCLUSION CRITERION: ***From concentrate, ready-to-feed, or not offering, check box***

11. Do you participate in the WIC program? □ No (0) □ Yes (1) ☐

If "no," continue to question 12.

If "yes," continue to question 13.

12. Do you receive Food Stamps? □ No (0) □ Yes (1)

If "no," ask:

13a. How many people are in your household? _____

13b. Based on the number given in 13a, find and circle the annual income on the chart.

Effective July 1, 2012 through June 30, 2013

Size of Family Unit	185% of Poverty
1	$20,665
2	$27,991
3	$35,317
4	$42,643
5	$49,969
6	$57,295
7	$64,621
8	$71,947
***For family units with > 8 members, add $7,326 for each additional person**	

13c. Ask: Is your household income less than or equal to _____?

□ Less than (1) □ Equal to (1) □ Greater than (0)

EXCLUSION CRITERION: ***If greater than, check box*** ☐

Appendix B: Recruitment Flyer

Appendix C: Script to Determine Interest for Eligible Participants

If **ELIGIBLE** for **Baby Mine Phase 2A – Home Interviews**:

I really appreciate your time spent answering these questions. Based on your answers, you are eligible to participate in one of our projects. Now I'd like to briefly explain what participating in this project means:

You would help us to learn more about mothers and babies by participating in an interview. You will be asked to do two things:

1. Show us how you make your baby's formula bottles
2. Complete a one-on-one recorded discussion about feeding babies

This will take place at your home and it will take 1 to 1 ½ hours to complete. There is no cost to you to participate, and you will receive **$20 in gift cards** after completing all of the study activities.

Would you be interested in participating in this project? ____ yes ____ no (if no, go to **REFUSAL**)

If yes,
Wonderful, may I please have your name? _____

Can we set up a date and time for the home visit? *(at least **3 days later**)*

_____

We will be mailing the consent form to you before the visit. Can we have your home address?
Address:

Best phone #: _____Best time to call this number: _____

May we leave a message at this number? ___ Y ____N

Alternate phone #: _____Who alternate phone belongs to: _____

May we leave a message at this number? ___ Y ____N

If parent **REFUSES**:
Could you please tell me why you don't wish to participate? This helps us to better design studies in the future.

_____
_____

Thank you so much for your time today. We appreciate your answering these questions and wish the best for you and your baby.

Appendix D: Informed Consent

INFORMED CONSENT STATEMENT (IRB# 7234B)

University of Tennessee Infant Study

INTRODUCTION

You are invited to participate in a research study. The purpose of this study is to learn more about babies.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

We will be recruiting parents or other caregivers of infants less than 12 months old and pregnant women. If you decide to volunteer, we will ask you to participate in the following activity:

> You will be asked to participate in one audio-recorded discussion of how parents and others interact with babies who are less than 12 months old. This conversation will occur either one-on-one or in a group with other parents. If one-on-one, it may occur in person or over the telephone.

RISKS

There are no risks to you for participating in this study.

BENEFITS

You will not personally benefit from this study, however this information will help us to understand more about how parents and other caregivers in East Tennessee interact with their babies and will be beneficial to future parents and their children.

CONFIDENTIALITY

The procedures for audio-taping include no identifying information to link you with the resulting audiotape or electronic text files. Your confidentiality will be maintained on the audiotapes and electronic files, therefore, because there will be no way we can learn your identity from the data collected. However, it is important for you to understand that the researchers cannot fully control confidentiality of research conducted in a group setting (should you participate in a group conversation and not a phone call). Confidentiality will be maintained to the best of our ability, but cannot be guaranteed after leaving the focus group setting. The project-related materials, including the audiotapes without identifiers, will be stored in a locked office on the UT campus. Only project staff will have access to data from the project. All audiotapes will be destroyed after 10 years.

Any information obtained in connection with this study will be used in a manner that does not publicly disclose your identity and will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

COMPENSATION

There is no cost to you to participate in this study. Participants will be compensated for their time and effort with a $20 gift card to a local department store. Compensation will be received upon completion of group discussion or phone call.

EMERGENCY MEDICAL TREATMENT

The University of Tennessee does not "automatically" reimburse subjects for medical claims or other compensation. If physical injury is suffered in the course of research, or for more information, please notify the investigator in charge, Katie Kavanagh, at 865-974-6250.

_____ Participant's initials

CONTACT INFORMATION
If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, Katie Kavanagh, at 229 Jessie Harris Building, and 865-974-6250. If you have questions about your rights as a participant, contact the Office of Research Compliance Officer at (865) 974-3466.

PARTICIPATION
Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed your data will be returned to you or destroyed.

CONSENT

I have read the above information. I certify that I am 18 years of age or older. I have received a copy of this form. I agree to participate in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

This consent form will be stored for three years past the completion of the study.

Appendix E: Infant Formula Preparation Checklist and Semi-Structured Interview Script

Introduction:

Thank you for agreeing to meet with us today. Just a quick refresher; we will do two things:

1. First, we'll ask you to show us how you make your baby's bottles

2. Then, we will ask you some questions about how you do that

The whole thing should take about an hour to an hour and a half. Once we're done with everything, we'll give you 2 $10 gift cards.

Before we start, we'll go over the consent form. Have you had time to look at it?
[Review form with subject]

Do you have any questions about the form?

Great, you can keep the one we sent to you, that's your copy. Please sign this copy for us to keep on file.

(Once they sign) Thank you. Do you have any other questions before we get started?

Observation:

Ok, let's start with the bottles. Please show us how you normally make your baby's bottle. You can talk us through it or just show us, whichever is more comfortable for you.
[Bottle 1: Bottle Prep Observation]

Great, thank you very much. Now will you show us how to make a bottle using this formula?
[Bottle 2: Bottle Prep Observation]

Do you ever add anything else to the bottle?
Yes: Can you show us how you do that? [Bottle 3: Bottle Prep Observation]
No [begin Interview]

Date: _____ Researcher Initials: _____ ☐Interviewer ☐Note-Taker

Bottle 1: Current Formula		
	Checklist	**Notes**
Environment	1. Location: ☐ Living Room ☐Kitchen ☐Bedroom ☐Other (note) 2. Distractions: ☐TV ☐Radio ☐Phone ☐Computer ☐People ☐None 3. Other people present: ☐No ☐ Yes (note) 4. Supplies from other room: ☐No ☐ Yes (note)	
Sanitation & Sterilization	1. Washed hands with soap and water: ☐No ☐Yes ☐Not Observed 2. Bottle equipment inspected: ☐No ☐Yes ☐Not Observed 3. Bottle washed with soap and water: ☐No ☐Yes ☐Not Observed a. If sponge/bottle brush used, disinfected: ☐No ☐Yes ☐N/A 4. Source of water: ☐Tap ☐Filtered ☐Bottled ☐Sterile baby water ☐Other (note) 5. Water boiled: ☐No ☐Yes 6. Bottle warmed: ☐No ☐Yes	
Formula Prep	1. In bottle first: ☐Water ☐Formula 2. Amount of water: ___ oz a. Water leveled: ☐Flat surface ☐At eye level ☐Quickly eyed ☐Already in bottle 3. Scoop from can used: ☐No (note) ☐Yes a. # of scoops: ___ b. Formula scoop: ☐Level ☐Unleveled c. Formula leveled: ☐Against can ☐Tapped ☐Used finger ☐N/A ☐Other (note) 4. Cereal in bottle: ☐No ☐Yes 5. Other additions to bottle: _____ 6. Shakes bottle: ☐No ☐Yes a. How long: _____ 7. More formula added: ☐No ☐Yes 8. More water added: ☐No ☐Yes	

Bottle 2: Lab Formula		
	Checklist	**Notes**
Environment	1. Location: ☐ Living Room ☐Kitchen ☐Bedroom ☐Other (note) 2. Distractions: ☐TV ☐Radio ☐Phone ☐Computer ☐People ☐None 3. Other people present: ☐No ☐ Yes (note) 4. Supplies from other room: ☐No ☐ Yes (note) 5. Read instructions on can: ☐No ☐Yes	
Sanitation & Sterilization	1. Washed hands with soap and water: ☐No ☐Yes ☐Not Observed 2. Bottle equipment inspected: ☐No ☐Yes ☐Not Observed 3. Bottle washed with soap and water: ☐No ☐Yes ☐Not Observed a. If sponge/bottle brush used, disinfected: ☐No ☐Yes ☐N/A 4. Source of water: ☐Tap ☐Filtered ☐Bottled ☐Sterile baby water ☐Other (note) 5. Water boiled: ☐No ☐Yes 6. Bottle warmed: ☐No ☐Yes	
Formula Prep	1. In bottle first: ☐Water ☐Formula 2. Amount of water: ___ oz a. Water leveled: ☐Flat surface ☐At eye level ☐Quickly eyed ☐Already in bottle 3. Scoop from can used: ☐No (note) ☐Yes a. # of scoops: ___ b. Formula scoop: ☐Level ☐Unleveled c. Formula leveled: ☐Against can ☐Tapped ☐Used finger ☐N/A ☐Other (note) 4. Cereal in bottle: ☐No ☐Yes 5. Other additions to bottle: _____ 6. Shakes bottle: ☐No ☐Yes a. How long: _____ 7. More formula added: ☐No ☐Yes 8. More water added: ☐No ☐Yes	

Bottle 3: Optional Additions		
	Checklist	**Notes**
Environment	1. Location: ☐ Living Room ☐Kitchen ☐Bedroom ☐Other (note) 2. Distractions: ☐TV ☐Radio ☐Phone ☐Computer ☐People ☐None 3. Other people present: ☐No ☐ Yes (note) 4. Supplies from other room: ☐No ☐ Yes (note)	
Sanitation & Sterilization	1. Washed hands with soap and water: ☐No ☐Yes ☐Not Observed 2. Bottle equipment inspected: ☐No ☐Yes ☐Not Observed 3. Bottle washed with soap and water: ☐No ☐Yes ☐Not Observed b. If sponge/bottle brush used, disinfected: ☐No ☐Yes ☐N/A 4. Source of water: ☐Tap ☐Filtered ☐Bottled ☐Sterile baby water ☐Other (note) 5. Water boiled: ☐No ☐Yes 6. Bottle warmed: ☐No ☐Yes	
Formula Prep	1. In bottle first: ☐Water ☐Formula 2. Amount of water: ___ oz a. Water leveled: ☐Flat surface ☐At eye level ☐Quickly eyed ☐Already in bottle 3. Scoop from can used: ☐No (note) ☐Yes a. # of scoops: ___ b. Formula scoop: ☐Level ☐Unleveled c. Formula leveled: ☐Against can ☐Tapped ☐Used finger ☐N/A ☐Other (note) 4. Cereal in bottle: ☐No ☐Yes 5. Other additions to bottle: _____ 6. Shakes bottle: ☐No ☐Yes a. How long: _____ 7. More formula added: ☐No ☐Yes 8. More water added: ☐No ☐Yes	

Demographic Questions:

1. **What is your ethnicity/race?**

☐American Indian/Alaska Native ☐Asian ☐Black/African American
☐Hispanic/Latino ☐ Native Hawaiian/Other Pacific Islander ☐ White/Caucasian
☐ Two or more races ☐Other: _____

---

2. **What is the highest grade of school you have completed?**

☐Primary (elementary) ☐Secondary (middle & high) ☐GED
☐Vocational/technical
☐ Some college ☐ College ☐ Graduate school
☐Other: _____

---

3. **What is your current employment status?**
   a. **[If working] Full-time or part-time?**
   b. **[If NOT] Do you plan on returning to work?**

☐Currently working
   ☐Full-time ☐ Part-time
☐ NOT currently working
   ☐ With no plan to return
   ☐ Planning to return to work full-time
   ☐ Planning to return to work part-time

---

4. **What is your marital status?**

☐Single ☐Married ☐Divorced ☐ Separated ☐ Living with Partner
☐ Widowed
☐ Other: _____

---

5. **Is this your first baby?** ☐No ☐ Yes

6. **Including your baby, how many children are in your household?** _____

---

7. **Have you ever breastfed this or another baby?** ☐No ☐ Yes

   [If YES]
   a. **Was it this baby that you breastfed?** ☐No ☐ Yes
   b. **For the most recent baby you breastfed, how long did you breastfeed?**

Interview:

Thank you. Now we'll get started with the interview and I'll turn on the recorder. Do you have any questions before we start?

You have become an expert at making bottles for your baby, but at some point you might not have been the expert.

1. Think back to the very first time you remember making a bottle. It may have been for your baby or someone else's baby. Please tell me how you learned to make a bottle.

[Probe] Will you explain some more?

   a. How did you feel?

[Probe: Were you comfortable with making a bottle; was it easier or more difficult than you thought it would be; how did you feel?]

   b. Who was there to teach you?

      i. How was he/she helpful?

INTENT: HOW THEY LEARNED AND A SENSE OF HOW MUCH REALLY NEEDS TO BE LEARNED ABOUT MAKING A BOTTLE (WAS IT TAKEN SERIOUSLY). WAS IT IN A FORMAL OR AN INFORMAL SETTING? CAN THEY PINPOINT A TIME OR WAS IT JUST SOMETHING "THEY HAVE ALWAYS KNOWN"?

[Transition] That is really great information. Thank you for sharing. Now we're going to talk about how other moms fix bottles and formula.
Some moms fix bottles differently depending on the situation. They might add more or less of some things or they might add something extra.

2. Think about how you normally make a bottle. When might you make a bottle differently?

[Probe] Think about the weather.

[Probe] Think about when you are out of the house.

[Probe] Think about the time of day.

INTENT: ARE THEY LIKELY TO MODIFY BOTTLES? DO THEY SEEM OPEN TO IT OR IS THIS JUST NOT DONE? QUESTIONS 4 AND 7 GET TO HOW THEY RATIONALIZE CHANGING/MODIFYING CONTENTS.

[Transition] Thank you for sharing how you make your baby's bottles. We'll talk a little more about preparation.

3. Not all moms boil the water they use to make formula. Why do you think the formula can says to boil the water?

[Probe if mom responds with "to kill bacteria"] What bacteria?

[Transition] Wonderful. Now we'd like to learn more about what might happen to a baby if moms change how the formula is prepared.

4. We know that some moms add extra water or less water to their formula. Tell me about what happens to a baby when EXTRA water IS ADDED to the formula? (diluted)

[Probe] Can you explain or tell us more about that?

   a. Tell me about what happens to a baby when LESS water IS ADDED to the formula? (more concentrated)

[Probe] Would you like to add anything else?

INTENT: HOW OPEN ARE THEY TO MANIPULATING CONTENTS. FIRST, WITH WATER, WHICH SEEMS HARMLESS OR DO THEY HAVE AN UNDERSTANDING THAT THIS IS NOT DESIRABLE. IF SO, DO THEY HAVE AN UNDERSTANDING OF WHY?

[Transition] Thank you for sharing all of this valuable information with us.

5. Sometimes different situations come up and moms need to switch their babies' formula. When do you think a mom would need to change formulas?

    a. If your baby has been on more than one kind of formula, how many different kinds has he/she been on?

    b. Tell us about the different kinds of formula your baby has been on.

    c. How did you decide to change formula?

[Probe] Did your baby not like the formula? Was he/she spitting up a lot? Having diarrhea? Just seemed gassy, uncomfortable, fussy?

INTENT: THIS GETS TO THE MINDSET OF PERCEPTION OF DIFFERENCES IN FORMULAS AND/OR SYMPTOMS TRIGGERING CHANGES. WE KNOW THIS HAPPENS, AND WE HEAR SOMETHING ABOUT WHY, BUT I DON'T THINK WE UNDERSTAND HOW THEY CHOOSE THE NEXT FORMULA(S). WHAT ARE THE SYMPTOMS, FROM MOM'S PERSPECTIVE? DO THEY GET RESOLVED ON NEW FORMULA? DO THEY HAVE TO GO TO ANOTHER FORMULA? ARE THESE ALSO THE MOTHERS WHO MODIFY FORMULA? THIS IS HYPOTHESIS-GENERATING AND VERY OPEN-ENDED.

[Transition] Great, thank you.

6. Some moms say that formula isn't enough for their young babies. Some moms say it is enough. Can you tell me what you think about this?

    a. What are some **other** reasons moms may think formula ISN'T enough for their babies?

        i. How do you make sure your baby is eating enough?

    b. What are some **other** reasons moms may think formula IS enough for their babies?

        i. How do you make sure your baby doesn't eat too much?

INTENT: THIS GETS TO THE PERCEPTION OF FORMULA ITSELF. WHAT I WAS SAYING ABOUT UNDERSTANDING PHYSIOLOGY, "STICKING TO THE RIBS", ETC. SO IS FLUID LESS FILLING THAN SOLID? IF A BABY IS NOT GROWING FAST ENOUGH, WOULD THEY CONCENTRATE THE FORMULA? [ASSUMING THIS IS THEIR OWN EVALUATION OF GROWTH AND NOT A HEALTHCARE PROVIDER]. WOULD THEY ADD MORE BOTTLES TO THE DAY? WOULD THEY THICKEN IT?

[Transition] Now we have a couple questions about bottles and nipples.

7. We know moms have lots of choices about the bottles and nipples they use to feed their babies.
    a. Please tell me about the kind or kinds of bottle you use.

[Probe with examples: brand, store, plastic, glass, etc.]

        i. What made you use this kind of bottle?

    b. How about the kind of nipples you use? Please tell me about that.

[Probe with examples: brand, fast flow, slow flow, etc.]

        i. What made you use this kind of nipple?

    c. Sometimes moms decide to use a different nipple. When do you think a mom would do that?

        i. If a nipple doesn't work well, what could a mom do to make it work better?

INTENT: THIS IS JUST GETTING AT HOW MALEABLE THEIR CHOICES ARE AND HOW LIKELY THEY ARE TO BE LOYAL TO ONE BRAND/SET-UP, OR TO SEEK OUT WAYS TO CONTROL HOW INFANT GETS BOTTLE CONTENTS.

[Transition] All of this information is so helpful. Thank you.

8. We know moms who put cereal in their baby's bottle do so for many different reasons. We've tried to make formula with cereal in the bottle and even used different nipples, but we couldn't figure out how to get the formula out of the bottle BECAUSE IT IS SO MUCH THICKER. Can you tell me how that works?

[Probe] How did you know how to do this?

[Probe – IF MOM IS ADDING CEREAL] How long can you wait to feed your baby after making a bottle with cereal in it?

INTENT: THIS IS REALLY ABOUT WHAT IS HAPPENING "ON THE GROUND" AND HOW THEY ACTUALLY MODIFY.

[Transition] Great, thank you.

9. Please think about a normal day with your baby and when you make formula bottles. Every mom is different - some make a big batch of formula for the whole day, some make one bottle at a time right before their baby is ready to eat. Please describe when you would start making a formula bottle.

    a. Please tell me about your feeding schedule, if you have one.

[Probe] How often do you feed your baby?

    b. How does the amount you feed your baby change?

        i. When would you feed your baby more or less? (morning vs. night time, traveling, etc.)

INTENT: JUST GETTING AT PATTERNS.

[Transition] You're being very helpful; we really appreciate your time. Just a couple more questions.

10. What are some reasons that moms might start to give their babies solid food?

[Probe] Can you explain that a little more?

[Probe if mother reports growth as the reason:] You stated that a baby might need solid foods because that baby is growing quickly. How would a mom decide solid food was a better option for her baby instead of another bottle of formula?

INTENT: ULTIMATELY, AMONG THOSE WHO GIVE REASONS RELATED TO GROWTH, EXPLORING WHY NOT ANOTHER BOTTLE.

[Transition] We really enjoy talking to moms about baby advice because moms learn a lot through life experience with their babies.

11. When it comes to feeding your baby, what do you know now that you wish you knew when your baby was first born?

    a. When it comes to feeding a baby, what advice would you give to a new mom?

    b. When it comes to feeding your baby, what's the best advice you've received?

        i. Who gave you this advice?

    c. When it comes to feeding your baby, what's the worst advice you've received?

        i. Who gave you this advice?

INTENT: VALUATION OF ADVICE FROM FRIENDS, FAMILY, DOCS, ETC.

[Transition] You've given us lots of good information, thank you so much. One last question.

12. Is powdered formula sterile?

[Probe] … Meaning free from bacteria.

__ Yes __ No

After answering all of our questions, do you have anything else you'd like to add?

[Questions related to Bottle Prep Observation if needed]
So I noticed when making the bottles earlier you _____.
Please tell us more about that.

[Transition] I know it may be difficult to do things as you normally would when someone is watching you.

When you made the bottles earlier, did you do anything differently because we're here?

Great, thank you again. If you don't have anything else to add, I'll go ahead and turn off the recording.

STOP recording!

Appendix F: Example of Field Notes

P2A11 Field Notes

Notetaker: BG

When we arrived at the apartment, P2A11 and her sister were in the living room with two babies. One of the babies was P2A11's and the other baby was her sister's. The babies were about 2 weeks apart in age. The sister lives with P2A11 at this time. P2A11 also has a 7-year-old son who was not present during the visit. During the bottle observation, there was no one present in the kitchen (where the bottles were made), but the babies were making a decent amount of noise in the next room over that may have been distracting to the mom. The kitchen and living room were separated only by a counter top. The sister and her baby left the apartment before the start of the interview. The TV was on for the first half of the interview but on a low volume. P2A11 turned off the TV after a while. She held the baby for most of the interview, and the baby slept at times. P2A11 did not feed the baby while we were there. She said it was not yet time for the baby to eat.

Appendix G: Flyer Sent to Study Participants Following Study Activities

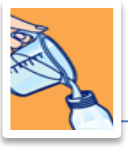
Making SAFE Formula

#1
Wash hands

#2
Use **clean** bottles and nipples

#3
Boil tap or bottled water

#4
Let the boiled water cool until **warm** to touch on wrist



#5
Add the **warmed** water to bottle before adding formula

#6
Measure the formula needed & **add** to water in bottle

#7
Shake well

#8
Ready to feed!

Mixing Formula Safely

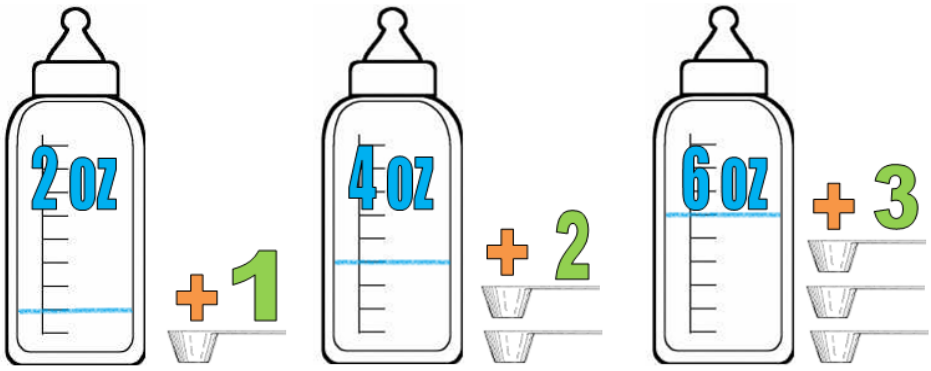
To avoid serious health problems & to help your baby grow well, make sure you are mixing formula safely!

Read directions on the back of the can

Check the expiration date

Do NOT use the microwave to heat

Every 2 ounces of water = 1 level scoop of formula



Appendix H: Reasons for Participant Ineligibility for Phase II

Reason for ineligibility	Frequency (n=120)
Not primarily offering powdered or from-concentrate infant formula	50% (60)
Infant >3 months of age	28% (34)
Income >185% Federal Poverty Level	24% (29)
Resides far from the University of Tennessee	13% (15)
Not the mother of an infant	8% (11)
Infant weighed less than 2,500 grams at birth	7% (8)
Infant had a health condition affecting infant intake	4% (5)
A combination of more than one of the above exclusion criterions	35% (42)

Total screened= 143 potential participants
Total ineligible= 84% (n=120)
Eligible and began study= 16% (n=23)
Eligible and completed study= 9% (n=13)

VITA

Rebecca Ellison graduated from the University of Georgia in May 2010 with a Bachelor of Science in Genetics and began graduate school at the University of Tennessee in August 2012. During graduate school, Rebecca served as a graduate research assistant for the Infant Child and Adolescent Nutrition (ICAN) Lab and also served as a funded trainee for the Maternal and Child Health (MCH) Nutrition Training Grant. Rebecca completed her 7-week block field experience at the Maternal and Child Health Bureau (MCHB), where she drafted a nutrition-focused, 5-year strategic plan for the Bureau. Rebecca is pursuing a dual master's degree: Master of Science (MS) in Public Health Nutrition and Master of Public Health (MPH) with a Health Policy and Management concentration. Her interests include maternal and child health, chronic disease prevention, public health policy, and program evaluation. Rebecca's long-term career goal is to work at the federal level addressing health disparities and other nutrition-related public health and policy needs.